§ 4079d

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124428
Facility ID:177436
Inspection ID #1774360008

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

02-BLT-15

April 25, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steven M. Gavalchik, C.E.O.
Webster County Memorial Hospital
324 Miller Mountain Drive
Webster Springs, West Virginia 26288

Dear Mr. Gavalchik:

We are writing to you because on April 19, 2002, a representative of the State of West Virginia, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violation of Section 354(f) of the Act **[42 USC 263b(f)]** at your facility, identified on your inspection report as a Level 1 finding:

- Your facility failed to produce documentation verifying th[redacted]net the initial requirement of being certified in diagnostic radiology or having had 3 months of training in the interpretations of mammograms **(21 CFR 900.12(a)(1)(i)(B)(1) and (2)).**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law, which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography (see Sections 354(h) through (j) of the Act).

In addition, there were Level 2 findings listed on the inspection report provided to you at the close of the inspection. A Level 2 finding indicates that the inspector found one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility. These Level 2 findings are:

- Your facility failed to produce documentation verifying that [redacted] M.D., and [redacted] M.D., met the initial requirement of having interpreted or multi-read 240 mammograms in a 6 month period **(21 CFR 900.12(a)(1)(i)(D)).**

- Your facility failed to produce documentation verifying that [redacted] M.D., met the initial requirement of having 60 hours of category 1 medical education in mammography **(21 CFR 900.12(a)(1)(i)(C)).**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. the specific steps you have taken to **correct** all of the violations noted in this letter; and

2. each step your facility is taking to **prevent the recurrence** of similar violations.

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Steven B. Barber, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Lee Bowers
Director, Baltimore District